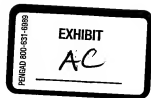


U.S. Patent Application No. 10/697,083

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:)
Wesley Scott Ashton) Atty. Docket: ASHTON0008
)
Serial No. 09/881,806)
) Group Art Unit: 3677
)
Filed: June 18, 2001) Examiner: CHOP, Andrea Marie
)
For: TONGUE AND MOUTH STUD)
FOR DISPENSING A)
SUBSTANCE)



DECLARATION UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D. C. 20231

1. I, Wesley Scott Ashton, M.D., state that I am an expert in the field of medicine and the research and development of medical devices as indicated by my attached curriculum vitae (see Appendix A).

Purpose of the Declaration

2. The purpose of the present declaration is to provide additional factual information from the prior art medical literature as a whole, and expert testimony, to show that one of ordinary skill in the art would not have a sufficient justification to combine the teachings related to prior art earrings to the field of mouth and tongue studs because (a) the prevalence of infected tongue piercing channels is virtually non-existent, and (b) even if the teachings were combined to make

the claimed device, there is no teaching to suggest that the device would have a reasonable expectation of success for its intended purpose because (i) the mouth is a different environment from the external ear (i.e., pinna and earlobe), (ii) the methods of prevention of tongue piercing infections are so different from the methods used to prevent ear piercing channel infections that it is not reasonable to apply the methods used to prevent ear piercing channel infections to an intraoral wound, and (iii) medical wisdom and experience would discourage the use of a tongue barbell device to treat an infected tongue piercing channel.

In other words, the facts and expert medical testimony presented in this declaration will show that it is an incorrect factual predicate to infer that methods and apparatuses used for preventing and treating ear piercing channel infections are applicable to preventing and treating tongue piercing channel infections.

Most Relevant Prior Art Cited by Examiner

3. I am familiar with the above captioned patent application and understand that certain prior art references were cited against the claims of the application. Specifically, I am familiar with the Denny et al. reference (U.S. Patent 6,047,209), the Piperato et al. reference (U.S. Patent 6,039,049), the Kaping, Jr. reference (U.S. Patent 6,026,659), the Edwards reference (U.S. Patent 4,943,274), the Parry reference (U.S. Patent 5,016,369), the Inuoe reference (U.S. Patent 5,632,163), and the Black reference (U.S. Patent 4,056,951).

I have relied upon the above patents and other materials cited herein as a basis for my expert opinion.

4. Search of the Medical Literature

On September 1, 2002, I performed a PubMed search (i.e., a MEDLINE search) of the publicly available online medical database provided by the National Library of Medicine (www.ncbi.nlm.nih.gov). The search terms included (a) “tongue ring” and infection, (b) “tongue barbell” and infection, (c) “tongue stud” and infection, and (d) “tongue piercing” and infection. The results of the search are provided in Appendix B. Copies of the relevant medical articles and references are provided in Appendix C.

Of the articles listed in the search results or in bibliographies of the articles retrieved, the following seven articles, which I relied upon to form my opinion, appear to be the most relevant and include:

- i. Perkins, C.S. et al.: A complication of tongue piercing. *Br. Dent. J.* 182:147-148 (1997).
- ii. De Moor, RJG et al.: Tongue piercing and associated oral and dental complications. *Endol. Dent. Traumatol.* 16:232-237 (2000).
- iii. Farah, C.S. et al.: Tongue piercing: Case report and review of current practice. *Aust. Dent. J.* 43:387-389 (1998).
- iv. Cobb, D.S. et al.: Adhesive Composite Inlays for the Restoration of Cracked posterior Teeth Associated with a Tongue Bar. *Pract. Periodont. Aesthet. Dent.* 10:453-460 (1998).
- v. Botchway, C. et al.: Tongue piercing and associated tooth fracture. *J. Can. Dent. Assoc.* 64:803-805 (1998).

- vi. Reichl, R. B. et al.: Intraoral body-piercing: a case report. Gen. Dent. 44:346-347, 1996.
- vii. Chen, M. et al.: Tongue piercing: a new fad in body art. Br. Dent. J. 172(3):87, 1992.

In addition, the following sections from four medical textbooks that I relied upon to make my opinion are included as background material.

- viii. Harwood-Nuss, A.L.: The clinical practice of emergency medicine (3rd ed.), Lippincott William & Wilkins, Philadelphia, 2001, pp. 477-478.
- ix. Gorbach, S.L. et al. (eds): Infectious diseases (2nd ed.), W.B. Saunders Co., Philadelphia, 1998, pp. 510-511, 1261-1262 and 1266.
- x. Champion, R.H. et al. (eds): Textbook of Dermatology, Vol. IV, Rev. ed., Blackwell Science, Inc., Malden, MA, 1998, pp. 3019-3020.
- xi. Schmidt, B.D.: Your child's health: the parents' guide to symptoms, emergencies, common illnesses, behavior, and school problems, Rev. ed., Bantam Books, New York, 1991, pp. 77-78, 80-82, and 524-527.

Lastly, I relied upon my almost 10 years as a practicing pediatrician, where I frequently encountered patients with mouth and tongue studs.

5. **Detailed Analysis of the Prior Art References and Medical Literature**

The most relevant prior art and most relevant medical literature will be briefly summarized for the record.

The Denny et al. reference (U.S. Patent 6,047,209) discloses a method and apparatus for maintaining pierced orifices; however, this technical disclosure is not directed to a device or

method for use in the mouth. Specifically, the reference teaches a device and method for reducing infection of the pierced orifice (col. 2, lines 4-16) and dispenses "salve, hydrogen peroxide, Polysporin" (col. 3, lines 34-36), which those skilled in the medicinal arts would recognize are treatments for skin injuries and not for intraoral trauma. The reference discusses "pierced orifices" (302), but the context makes it clear that a "pierced orifice" is a channel made in a body part (col. 4, lines 25-40, Figure 3) and does not suggest an intraoral piercing. The reference does not teach anything about tongue and mouth studs. Furthermore, one skilled in the art would realize that the needle and rings disclosed by the Denney et al. reference are not tongue and mouth studs because they do not include structure to maintain them in a wearer's tongue, such as by means of threaded caps taught by the Kaping, Jr. reference.

The Piperato et al. reference (U.S. Patent 6,039,049) discloses a nose ring (12), a nipple ring (14) and a naval ring (16). The Piperato et al. reference does not appear germane to the topic of tongue and mouth studs.

The Kaping, Jr. reference (U.S. Patent 6,026,659) discloses a bar bell stud (10) for use in a wearer's tongue (Figure 1, col. 3, lines 38-54).

The Edwards reference (U.S. Patent 4,943,274) discloses an apparatus for applying earlobe medication, such as "antibiotic gel, petroleum or aloe-based ointments" (col. 2, lines 22-24), which those skilled in the medical arts would recognize are treatments for infections of a piercing channel in an earlobe.

The Parry reference (U.S. Patent 5,016,369) discloses tag assemblies for tagging of the ears of livestock using a special fitting tool that includes a piercing part (15) so that the piercing part (15) fits through the center of the tag (1) as evident from Figures 1 and 2 (col. 1, lines 6-8,

lines 45-59, and col. 3, lines 6-28). The device can be used to administer various medications into the wound in the animal's ear (col. 1, lines 41-68). However, there is nothing in the reference that teaches one skilled in the art that such a tag assembly would be placed in the mouth. Furthermore, those skilled in the medical arts are aware that tongue piecing causes significant swelling of the tongue, which is much more dramatic than that which occurs after piercing an ear. Consequently, it is unlikely that those skilled in the art of tagging animals would use the device taught by the Parry reference in an animal's mouth. Furthermore, although the Parry reference discusses using the device to topically apply systemic medications to the wound (col. 1, lines 53-59), those skilled in the medical and pharmacological arts would realize that applying a medication to a wound is not a conventionally accepted method for administering systemic medications, especially in view of the fact that there are more reliable and efficient methods of administering parenteral medication.

The Inuoe reference (U.S. Patent 5,632,163) discloses a pierced earring hole maintenance device for maintaining a small opening formed in the earlobe (see Abstract). The devices (1), (41) shown in Figures 1, 9 or 13 are constructed for use in earlobe piercing (col. 4, lines 31-34, and col. 5, lines 28-35). The device can be taped into place (col. 4, lines 25-31), or a fastener (11) can be used. The fasteners (11) shown in Figures 9, 13, 16 and 18 all appear to use a frictional fit to maintain the fastener attached to the pierced earring hole maintenance device. Those skilled in the art would recognize that none of the various embodiments of the fastener and pierced earring hole maintenance device are suitable for use in the mouth because the attachment between the fastener and the device is not strong enough to maintain the attachment if used in this environment. The fastener and pierced earring hole device

combination taught by the Inuoe reference would present a serious aspiration risk if applied to the mouth environment.

The Black reference (U.S. Patent 4,056,951) discloses a pierced earring having perfuming means as shown in Figures 1, 2, 4 and 6. Presence of the post (22) structure, which is illustrated in Figure 22, is clearly a pin for attaching to a nut (24) in a frictional manner. Those skilled in the art would realize that the use of pins in the mouth is inherently dangerous and such structure would be avoided. In addition, the Black reference teaches "means for dispensing a perfuming agent" (col. 3, lines 23-56) and those skilled in the art would recognize that perfume is not dispensed into the mouth.

The Perkins et al. article is a case report of Ludwig's angina that occurred four days after the placement of a metal barbell in the patient's tongue (p. 147, col. 1, lines 10-19). The patient was initially treated with oral amoxicillin and subsequently required admission to the hospital for endotracheal intubation, intravenous antibiotics, and surgical decompression of the floor of the mouth after removal of the barbell from the tongue (p. 147, col. 2, lines 3-26). This case is the only one of its kind and underscores the seriousness of Ludwig's angina (p. 148, col. 2, lines 6-11). The article also points out that Ludwig's angina is a relatively rare spreading cellulitis that involves the floor of the mouth (i.e., submandibular, sublingual and submental facial spaces)(p. 148, col. 1, line 2 to col. 2, line 5), which is not primarily a tongue infection and does not suggest that the problem is related to infection of a tongue wound. In fact, the article points out that sublingual trauma is a known risk factor as are dental causes (p. 148, col. 1, line 6 to col. 2, line 5). Those skilled in the medical arts would appreciate that the mechanism of disease in this case is likely to be trauma to the floor of the mouth secondary to

the metal barbell subsequently resulting in the rare complication of Ludwig's angina. There is no evidence in this article to suggest that the primary mechanism of disease was infection of the piercing channel in the tongue.

This case does not stand for the proposition that tongue piecing channel infections are common and it does not stand for the proposition that a tongue piercing channel infection is the cause for Ludwig Angina.

The De Moor et al. article presents a series of cases illustrating a spectrum of dental complications resulting from oral piercings, and that the most common complication is chipping of teeth (see Abstract). The article reports one case of a dental abscess that may have occurred secondarily to tooth fracture due to having a tongue piercing (see Case 3, p. 234-236). The article reviews the risk of hepatitis, HIV, tetanus, syphilis, and tuberculosis due to unregulated tongue piercings (p. 236, col. 2, lines 27-30). However, those skilled in the medical arts would realize that hepatitis and HIV are blood borne viral pathogens and that these infections can only be prevented by using uncontaminated instruments. Those skilled in the medical arts would realize that tetanus can only be prevented by proper immunization. Those skilled in the medical arts would also know that while syphilis and tuberculosis are bacterial pathogens, they are not preventable by application of creams, ointments, mouthwashes or other topical therapies. Lastly, the article warns generally about the hypothetical risk of infection after piercing and the serious risk it would pose to the airway (p. 236, col. 2, lines 35-37); however, the article does not report a single case of an infected piercing channel in the tongue.

The Farah article presents a relatively uncomplicated case report of a tongue piercing and the speech, mastication and swallowing difficulties that may occur (p. 388, col. 1, lines 12-14). The article points out that following intraoral piercing Cepacaine mouthwash may be used after meals (p. 388, col. 1, lines 2-4), and those skilled in the art would recognize that the practice is intended to promote good oral hygiene and to decrease the risk of infection after tongue piercing (see p. 388, col. 2, lines 37-40). This article reviews many complications of tongue piercing including viral and yeast infections (p. 388, col. 2, lines 32-36), and lists infection as a possible adverse consequence of oral piercing in Table 1. However, the Farah article does not report a case of a tongue piercing channel infection, nor does it shed any factual light on this issue.

The Cobb article presents a case of dental restoration following a cracked tooth secondary to a tongue bar (see Abstract). The article does not present a case of an infected tongue. The article points out that typical instructions following tongue piercing include rinsing after eating with Listerine and using a peroxide rinse twice daily (p. 459, col. 2, lines 18-24) and mentions that the use of 0.1% chlorohexidine gluconate has been used as adjunct therapy for infection following placement of a tongue appliance and cites the Chen article (p. 459, col. 2, lines 24-26). This article does not stand for the proposition that tongue channel infections are common or treatable using the same methods as for treating earring infections.

The Botchway article presents a case of tooth fracture following insertion of a barbell in a tongue (see Abstract). The article does not present a case of an infected tongue. The article also generally reviews the potential risk of viral infection, tetanus, syphilis,

tuberculosis, septicemia and toxic shock syndrome following body piercing (p. 4, lines 30-34, and p. 5, lines 3-5).

The Reichl article presents a relatively uncomplicated case report of a tongue piercing (see Abstract). The patient reported having swallowed part of the barbell (p. 346, col. 2, lines 26-30). The Reichl article does not report a case of infection, although the author warns "threats of infection, edema, and airway infection are significant" (p. 347, col. 1, lines 9-11). Those skilled in the art would recognize that the risks listed in this article represent merely an unsubstantiated opinion. This article does not stand for the proposition that tongue piercing channel infections are known or that treatments for earring channel infections are applicable to tongue piercing channel infections.

The Chen article reports the case of a tongue barbell. The patient was examined for pericoronitis caused by a partially erupted tooth when the dentist noted the tongue barbell (p. 87, col. 1, lines 19-27). The tongue barbell had been in place for about 6 months when the patient went to the dentist (p. 87, col. 1, lines 19-33). The patient recalled that during the first 2 months after the tongue piecing, the wound became "infected" and she had to milk "pus" out of the wound, which she kept clean with proprietary 0.2% chlorhexidine mouthwash until the wound healed (p. 87, col. 1, lines 40-50). Those skilled in the medical arts would realize that laypersons are not reliable sources of medical information. While it may be possible that this patient did have a tongue piercing channel infection that was successfully treated with mouthwash, it is also possible that the patient merely had a persistent serous discharge, a mucocele created by the trauma, or was simply expressing retained food particles from the wound, which she interpreted as "pus." In other words, those skilled in the medical arts

would be skeptical of the patient's hearsay report because the "infection" was not confirmed by a medical professional. Therefore, this case does not stand for the proposition that tongue piercing channel infections are common, or that they exist at all, because the reported case was never confirmed by a medical professional.

The Clinical Practice of Emergency Medicine textbook (hereafter, the "CPEM text") points out that a general approach to managing intraoral wounds includes a soft diet, warm saline rinses four times a day, the use of penicillin or clindamycin, and possibly the addition of an anti-staphylococcal antibiotic such as dicloxacillin or cephalexin if the wound is a "through-and-through" wound through the mouth (p. 477, col. 2, lines 40-47). Those skilled in the medicinal arts would realize that penicillin, clindamycin, dicloxacillin and cephalexin are all orally administered systemic antibiotics. Those skilled in the medical arts would know that the saline rinses would utilize 1 or more ounces of saline.

The Infectious Diseases textbook (hereafter, the "ID text") establishes that the flora of the mouth is unique and includes large numbers of anaerobic bacteria of low virulence, some aerobic *Streptococcus* species, *Actinomyces* species, etc. (p. 510, col. 1, lines 2-48), whereas skin infections usually involve either *Staphylococcus aureus* or *Streptococcus pyogenes* (p. 1261, Table 131-1, and p. 1262, col. 1, lines 38-56). The ID text also points out that topical antibiotics, such as mupirocin, bacitracin, and neomycin-bacitracin formulations are used to treat localized non-bullous impetigo skin infections (p. 1266, col. 2, lines 8-21).

On the other hand, the ID text describes Ludwig Angina as a rapidly spreading phlegmon or cellulitis involving the floor of the mouth and loose areolar tissue, usually occurring in patients with abscessed teeth or pyorrhea, although inflammation of the tongue or

floor of the mouth may be another cause (p. 511, col. 1, lines 4-15). Ludwig angina is generally treated by securing the patient's airway by endotracheal intubation and administering intravenous antibiotics (p. 511, col. 1, lines 49-57).

The Textbook of Dermatology (hereafter, the "Derm text") establishes that the most common adverse effects of ear piercing are contact dermatitis, inflammation, bleeding, non-purulent drainage and infection, and that localized bacterial infection with gram-positive cocci is common (p. 3019, col. 1, lines 24-37). The Derm text stands for the proposition that localized bacterial infections of ear piercing channels are common.

The Your Child's Health text (hereafter, the "YCH text") establishes that infections of mouth injuries are rare, although cuts of the tongue may be common (p. 77, lines 17-22). The YCH text recommends a soft diet and rinsing the mouth out with water well after meals as appropriate treatment after minor intraoral trauma (p. 78, lines 17-23). On the other hand, the YCH text points out that the most common complication of pierced ears is a bacterial infection of the channel that is generally treated by good earring hygiene and the use of bacitracin ointment applied to the post of the earring (p. 524, last line, to p. 526, line 3).

This textbook stands for the proposition that while ear piercing channel infections are common, tongue infections are rare. Furthermore, the YCH textbook stands for the proposition that earring channel infections are treated differently from wounds in the mouth.

6. **Summary Analysis of the Medical Literature**

The state of the medical art at the time of the filing of Patent Application No. 09/881,806 is summarized in Table 1 below and is discussed as follows.

TABLE 1

	Ear Rings	Mouth and Tongue Studs
Environment of Use	The pinna or lobe of the ear, generally dry.	The mouth and tongue, generally exposed to saliva and wet.
Environmental Flora	Mostly aerobic, high virulence <i>Staphylococcus Aureus</i> , <i>Streptococcus pyogenes</i> (Sherwood, pp. 1261-2).	Mostly anaerobic, low virulence fusobacteria, pigmented <i>Prevotella</i> species, anaerobic streptococci or <i>Peptostreptococcus</i> species, <i>Eikenella</i> species, <i>Actinomyces</i> species, and some aerobic <i>Streptococcus pyogenes</i> (Sherwood, p. 510).
Most Common Complication	Local infection (impetigo) of the piercing channel, (Schmidt, pp. 524-6)	Chipping of teeth (De Moor, Abstract). Local infection of a mouth injury is rare (Schmidt, p. 77).
Prevention of Infection	Good skin hygiene, topical antibiotic ointment or cream is optional (Schmidt, pp. 81 and 526).	Good oral hygiene, soft diet, rinse mouth with water or mouthwash (Farah, p. 388; Schmidt, p. 78). Consider oral antibiotic (Harwood-Nuss, p. 477).
Treatment of Infection	Good skin hygiene, remove and clean ear rings several times a day, apply topical antibiotic ointment or cream to earring post and reinsert into piercing channel (Schmidt, p. 525-6).	Good oral hygiene, removal of tongue barbell , systemic oral antibiotic, possible hospital admission for intravenous antibiotics and endotracheal intubation to secure airway (Perkins, p. 147)

First, the most common complication of pierced earrings is a local infection (i.e., non-bullous impetigo) of the piercing channel, whereas the incidence of a local infection of the piercing channel of the tongue is virtually non-existent. In fact, no confirmed case of a

tongue piercing channel infection was uncovered in the present search of the online worldwide medical database of the U.S. National Library of Medicine.

One skilled in the medical arts would recognize that the earlobe is a dry aerobic environment that includes highly virulent staphylococcal and streptococcal bacterial species, whereas the mouth is a more anaerobic environment that includes lower virulent mixed bacterial species. Therefore, the pathophysiology of ear piercing channel infections and tongue piercing channel infections is different.

Second, the incidence of tongue piercing channel infection is so low that it is essentially non-existent. The medical literature points out that an infected tongue is a serious event, and those skilled in the medical arts would recognize this because an infected tongue would result in tongue swelling, which is a potentially life-threatening complication that can cause compromise of the patient's airway. However, the medical literature worldwide also documents no more than a theoretical risk of bacterial channel infection following tongue piercing. Specifically, the Chen article reports the only possible case of an infected tongue piercing channel; however, the "infection" is based upon the patient's recall of events and no qualified health care provider ever confirmed the diagnosis. Many of the medical articles discussed above include general warnings about the serious risk of infection that follows tongue piercing; however, these statements represent no more than vague general opinions because these cases do not provide facts to substantiate a real palpable risk for tongue piercing channel infections.

Specifically, the medical literature points out the general risk of virally transmitted blood borne disease from unsterilized instruments (see the Botchway article, the De Moor

article, and the Farah article). With respect to bacterial infections, the medical literature properly documents only one dental abscess due to tooth fracture following an oral piercing (see De Moor article) and one case of Ludwig Angina following placement of a metal barbell in a patient's tongue (see Perkins article). It is not clear from the Perkins article if placement of the metal barbell caused a dental injury leading to a dental abscess that caused the Ludwig Angina, or if the metal barbell caused direct inflammation of either the tongue or the floor of the mouth that progressed to Ludwig Angina. Either way, the medical literature does not clearly document even one case of an infected tongue piercing channel.

Those skilled in the medical arts would expect that if tongue piercing channel infections were commonplace, then there would be ample medical literature describing the etiology, diagnosis, treatment and prevention of what would be a serious, life-threatening infection. Because this body of evidence is lacking from the medical literature despite the recent popularity of tongue piercing over the past 10 years in the United States and Europe, those skilled in the medical arts, such as myself, would conclude that tongue channel infections due to metal barbell piercings are an exceedingly rare medical oddity. Perhaps they do not even exist at all. In other words, tongue piercings may have their risks and complications, but in my medical opinion, given that thousands, if not millions, of people worldwide have had their tongues pierced with no reported channel infections, it is reasonably inferred that piecing channel infection is not a significant risk. In fact, I have never personally encountered a case of an infected pierced tongue in my own medical practice, and I do not personally know of any medical colleague who has encountered such a case. My medical experience, and my medical opinion, are supported by the complete lack of properly

reported medical cases of pierced tongue channel infections in the worldwide medical database of the National Library of Medicine.

Third, even if tongue piercing channel infections were commonplace, which they are not, skin injuries and intraoral injuries are managed differently. Minor skin wounds are managed with good skin hygiene and, optionally, topical antibiotics. Minor localized non-bullous skin infections, such as an earring piercing channel infection, may be managed with a topical anti-biotic ointment. The earring wearer, in many cases, can continue to wear earrings during treatment. On the other hand, intraoral wounds are managed with (a) a soft diet to avoid additional trauma, (b) good oral hygiene to include washing out the mouth with water or an anti-septic mouthwash after meals to keep food out of the wound, and optionally (c) a peroxide rinse twice daily to keep the bacterial load in the mouth down. However, application of antibiotic ointments to intraoral wounds is simply not done. Such antibiotic ointments are petroleum based, or are in a lipophilic base, and would be repelled by the saliva on the mucosal surfaces of the mouth. Furthermore, the copious production of saliva in the mouth would quickly wash away any antibiotic or antiseptic substance dispensed locally by a tongue barbell so that whatever small volume of such a substance could be dispensed locally would be so minute and diluted as to be therapeutically ineffective for the purpose of either preventing, or treating, a tongue piercing channel infection. Those skilled in the medical arts would realize that mouth rinses with water, saline or mouthwash typically utilize doses of about 1 ounce (30 cc) or more. It is not conceivable that a tongue barbell could contain this amount of fluid.

And fourth, in view of the one case of Ludwig Angina reported, and the teachings of the ID text, it is suggested that management of a tongue infection would include hospitalization, endotracheal intubation, and intravenous antibiotic. Any metal barbell would be removed according to the Perkins article and there is nothing in the medical literature to suggest that it would be prudent to leave any form of bar bell device in the piercing channel of the infected tongue. In fact, medical common sense would dictate that the marked degree of tongue swelling that accompanies tongue infection would compel a medical practitioner to remove all barbells even if that meant the piercing channel would close in a few hours.

7. **Evidence Based Medical Conclusion**

In my expert medical opinion, based upon over 10 years clinical experience and objective data available in the medical literature, while bacterial earring channel infections are commonplace, tongue piercing channel infections are either non-existent, or at most exceedingly rare. In addition, preventive measures taken to prevent earring piercing channel infections may include the application of topical antibiotics in ointment, cream or gel forms, either by direct application to the ear piercing channel, or by application to the post of an earring, or by using one of the modified earring devices for dispensing an antibiotic ointment. However, preventive measures taken to prevent tongue piercing channel infections are substantially different from preventive measures taken to prevent ear piercing channel infections because the environment and pathophysiology in which intraoral infections occur is substantially different from that in which earring channel infections occur. Most notably, copious amounts of mouth rinses or antiseptic mouthwashes are used to keep food particles

out of the tongue piercing channel and antibiotic ointments and creams are not used. In fact, antibiotic rinses are not used in the mouth either. The local application of a topical antibiotic is not used in the mouth probably because the production of saliva in the mouth would dilute its effect.

Lastly, given the concern that exists regarding tongue swelling and airway compromise during a tongue infection, the use of any sort of tongue barbell device for treatment of an infected tongue would be medically contraindicated as evidenced by the Perkins article. Therefore, while earrings may remain in place during treatment of many earring channel infections, medical recommendations during treatment of tongue infections would include removal of any tongue barbell as part of treatment.

8. **Synopsis of the Prior Art and the Medical Literature**

The Kaping, Jr. reference teaches that barbell studs for use in the tongue were known at the time the present invention was made. The Edwards reference teaches a prior art earring that has structure for dispensing medication, either an antibiotic gel, petroleum or aloe-based ointment, to prevent or treat an earring channel infection. The other prior art patents teach variations on the Edwards theme and are more or less duplicative except for the Black Patent, which teaches an earring for dispensing perfume. Those skilled in the art would realize that perfume is used for external use only and is not ingested. The YCH text teaches that earring channel infections of the earlobe are commonplace and can be effectively treated by applying an antibiotic ointment to the post of the earring. On the other hand, the worldwide medical literature, taken as a whole, suggests to those skilled in the art that tongue piercing channel infections are exceptionally rare. Furthermore, the Perkins article and the ID text suggest that tongue infections are serious and that placement of any bar bell device in the piercing channel of an infected tongue would be contraindicated. Thus, considering the state of the art at the time the invention was made, those skilled in the art would realize that there was no need for a metal barbell device that would dispense an antibiotic to the piercing channel of the tongue because (a) the incidence of infected tongue piercing channel infections is so rare as to be no motivator at all, (b) prevention of such infections involves the use of antiseptic mouthwashes and peroxide rinses in volumes so large as to preclude the use of a metal bar bell device on account of its small volume, and (c) medical wisdom and the teachings of the Perkins article suggest that placement of any bar bell device in the piercing channel of an infected tongue would be medically contraindicated.

From the synopsis of the prior art and the medical literature, it is established that any inference that methods and apparatuses used for preventing and/or treating earring channel infections are applicable to preventing and/or treating tongue piercing channel infections is an incorrect factual predicate.

I declare under penalty of perjury that the foregoing is true and correct, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed by,

Date: June 17, 2003

W. J. Schaefer MD

Appendix A

WESLEY SCOTT ASHTON, M.D.

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PROFESSIONAL RECORD

Physician Management, Ltd. (part-time)

August 01-present
Bethesda, MD

PHYSICIAN

Providing general medical care as housestaff physician to St. Mary's Hospital inpatients. Patients' ages ranging from birth to geriatrics. Responsible for attending cesarean sections and high risk deliveries to provide newborn resuscitation. Responsible for inpatient trouble shooting and to provide in house coverage for inpatient emergencies, including ACLS, PALS, and NALS emergencies. Also providing express care services to include management of acute medical problems and minor surgical problems. Averaging 5 plus patients per hour in express care setting.

Griffin & Szpil, P.C.

June 01-present
Arlington, VA

PATENT AGENT

Patent Agent in general intellectual law practice. Responsible for crafting patent applications in a variety of mechanical and electrical arts. Responsible for prosecuting patent applications before the U.S. Patent Office. Also responsible for legal research and material preparation for patent law attorneys in mechanical and chemical art cases.

Children's Medical Group

October 99-June 01
Cumberland, MD

PEDIATRICIAN

General Pediatrician in 6 physician pediatric group. Provided well care, acute and chronic medical management and minor surgical care to children from birth to age 21 years. Averaging 5 plus patients per hour. Also responsible for inpatient care in level II nursery and pediatric ward at local hospital. Responsibilities including stabilization and transfer of patients requiring level III NICU or PICU care. Infection Control Committee member, Memorial Hospital, October 99-June 01.

United States Patent and Trademark Office

October 98-October 99
Arlington, VA

PATENT EXAMINER/PHYSICIST

Responsible for determining patentability of inventions pertaining to the musical technologies. Performed specialized technical searches of patent and research databases, collected data for the public record, determined patentability of inventions by interpreting patent law and the technology, prepared complete, concise technical and legal reports. Achieved 100% production goal and was promoted to GS-11 position.

Dewitt Army Community Hospital Fort Belvoir

October 96-September 98
Ft. Belvoir, VA

PEDIATRICIAN

Provided Outpatient and Inpatient Pediatric Care in level II hospital with 6 bed ICU capability and 20 bed level III Nursery supporting 1200 deliveries annually. Additional responsibilities lecturing and mentoring Family Practice Residents during inpatient pediatric rotations each month. Lectured and supervised medical students and clinical nurse

practitioner students. Eight months working in busy level II Emergency Department with over 40,000 visits per year, caring for patients of all ages and with full spectrum of medical, surgical and psychiatric emergencies. Honorable Discharge, September 1998.

**Bassett Army Community Hospital
Fort Wainwright**

July 94-September 96
Fairbanks, AK

PEDIATRICIAN

Provided outpatient and inpatient pediatric care in 22 bed level II hospital with level II nursery supporting 750 deliveries per year in a remote location. Chief, Department of Medicine, March-September, 1997, supervised 9 health care providers and 25 paraprofessional personnel. Managed operating budget of \$320,000. Interim Chief, Department of Pediatrics, June-August 1995, supervised 3 health care providers and 4 paraprofessional personnel. Managed operating budget of \$45,000. Prepared department for JCAHO, contributing to the Hospital's most successful JCAHO, Accreditation with Commendation. Improved quality of hospital inpatient chart documentation while a member of the Medical Records Review Committee. Received an Army Commendation Medal for providing excellent medical care during my assignment to Ft Wainwright, as well as to acknowledge contributions to the successful JCAHO inspection. Received Army Achievement Medal for providing excellent medical care to troops in the field during a simulated desert warfare environment at the National Training Center in Feb 95. Graduated from the Army Officers' Advanced Course, with Honors, Mar 96.

Walter Reed Army Medical Center

July 91-June 94
Washington, DC

Pediatric Resident, July 1992-June 1994. Received Army Achievement Medal for research on growth factor modulation by testosterone on a *in vivo* cell model.
Pediatric Internship, July 1991-June 1992.

Walter Reed Army Medical Center

April-May 1990
Washington, DC

Active duty training in Pathology, with additional training in fine needle aspiration biopsy, frozen section techniques and cytology.

**Moncrief Army Community Hospital
Fort Jackson**

June-July 1987
Columbia, SC

Active duty training with rotations in Preventive Medicine and Otolaryngology.

**Student Fellow, Institute of Pathology
Case Western Reserve University**

1988-89
Cleveland, OH

One year fellowship in Anatomical Pathology and Research. Performed twelve autopsies. Research focusing on the histochemical properties of colon polyp subsets using tissue from surgical specimens embedded in plastic. Experience with tissue processing, glycol methacrylate embedding and cutting techniques, histochemical and immunohistochemical staining techniques.

LICENSES AND CERTIFICATIONS

Pediatrics Board Certified, OCT 94; recertified 2001
National Board of Medical Examiners, parts I,II,III, completed in 1992
Medical Licenses: Maryland, Virginia
Maryland Controlled Dangerous Substances License. MAY 98.

Drug Enforcement Agency Controlled Substance Registration Certificate, JUN 98.
Fellow of the American Academy of Pediatrics
Patent Agent, Registered with the U.S. Patent and Trademark Office, Reg. #47,395

EDUCATION

Doctor of Medicine
Hahnemann University

June, 1991
Philadelphia, PA

Alpha Omega Alpha Medical Honor Society.
Honors in Anatomy, Biochemistry, Medicine, Surgery, and Psychiatry.
President, Medical Student Institute (Student Government), 1987-88.
School of Allied Health Professions Honor Award, 1988.
Treasurer, 1990 Medical Note Service, Budget \$40,000/year, 1986-88.
Vice-President, Class of 1990, 1986-87.

Master of Science in Physics
State University of New York
at Binghamton

May, 1986
Binghamton, NY

Sigma Pi Sigma Physics Honor Society.

Thesis: "A Computer Solution of the Theoretical Bose-Einstein Condensations in Biological Systems."

Bachelor of Arts, Major: Physics
Hamilton College

May, 1984
Clinton, NY

PRESENTATIONS

Ashton, W. S., Dykstra, K. D., and Francis, G. L.: *Testosterone Increases the In Vitro Production of Insulin-like Growth Factor 1 and Insulin-like Growth Factor Binding Protein by Neonatal Foreskin Fibroblasts*. American Pediatric Society/Society for Pediatric Research. May 1993.

Ashton, W. S., Sariego, J., Byrd, M., Matsumoto, T., Polansky, M., and Kerstein, M.: *A Multivariate Analysis of Colon Cancer, Preoperative Carcinoembryonic Antigen Levels, and Patient Survival*. American College of Gastroenterology. October 1991.

Ashton, W. S., O'Riordan, M. A., and Pretlow, T. P.: *Phenotypic Alterations in Benign Human Colonic Epithelial Cells*. FASEB. March 1989.

PUBLICATIONS

Ashton, W. S., Adkins, C. S., Delzer, D. R.: "Flocculus Neonatorum": A Self-Resolving Benign Nodular Flocculus of the Iris in the Newborn. *Clin Pediatrics* 37:1998, 323-326.

Fairchok, M. P., Ashton, W. S., Fischer, G. W.: Carriage of Penicillin-Resistant Pneumococci in a Military Population in Washington, DC: Risk Factors and Correlation with Clinical Isolates. *Clin Infect Dis* 22:1996, 966-972.

Ashton, W. S., Degnan, B., Daniel, A., and Francis, G. L.: Testosterone Increases Insulin-like Growth Factor-1 and Insulin-like Growth Factor-binding Protein. *Ann. Clin. Lab. Sciences* 25:381-388, 1995.

Contributing author to DeFrank, J. J., et al. Nonionizing Radiation, Chap. in Textbook of Military Medicine. Part III, Vol. 2, edited by D.P. Deeter and J.C. Gaydos. Washington, DC: U.S. Government Printing Office, 1993.

Ashton, W. S., Puntel, R. A., Wiswell, T. E.: A Rapid and Readily Available Repair of the Peripherally Inserted Central Catheter in the Nursery. *Neonatal Intensive Care* 6:1993, 52-53.

Ashton, W.S., Sariego, J., Byrd, M., Matsumoto, T., Polansky, M., and Kerstein, M.D.: A Multivariate Analysis of Colon Cancer, Carcinoembryonic Antigen Levels, and Patient Survival. *Contemp Surg* 43:1993, 11-17.

Pretlow, T. P., Barrow, B. J., Ashton, W. S., O'Riordan, M. A., Pretlow, T. G., Jurcisek, J. J., and Stellato, T. A.: Aberrant Crypts: Putative Preneoplastic Foci in Human Colonic Mucosa. *Cancer Research* 51:1991, 1564-1567.

PATENTS

U.S. Patent 6,268,554: Music Box Comb Structure for Playing Duets.

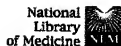
U.S. Patent 6,454,788 B1: Method and Apparatus for Oral Hydration and Medication Administration using a Pacifier Apparatus.

U.S. Patent 6,379,650 B1: Technetium 99m-N₂S₂-Congo Red Complexes Utilizing Diamide Dithiolate Ligand Systems for Radioimaging.

INTERESTS

Boating, fishing, camping and poetry. Poems "Aubade" and "Zoe" published in the 1990 edition of Handprints, and "Moonbeam" published in the 1991 edition.

Appendix B



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☐ 1: Dudkiewicz Z, Sekula E, Nielepiec-Jaloszinska A.

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Gastroesophageal reflux in Pierre Robin sequence—early surgical treatment.
Cleft Palate Craniofac J. 2000 Mar;37(2):205-8.
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Aust Dent J. 1998 Dec;43(6):387-9.
PMID: 9973706 [PubMed - indexed for MEDLINE]

☐ 2: Botchway C, Kuc I.

Related Articles, NEW Lir

Tongue piercing and associated tooth fracture.
J Can Dent Assoc. 1998 Dec;64(11):803-5. Review.
PMID: 9879145 [PubMed - indexed for MEDLINE]

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- ☐ 1: McGeary SP, Studen-Pavlovich D, Ranalli DN. Related Articles, NEW Lir
Oral piercing in athletes: implications for general dentists.
Gen Dent. 2002 Mar-Apr;50(2):168-72.
PMID: 12004711 [PubMed - indexed for MEDLINE]

- ☐ 2: De Moor RJ, De Witte AM, De Bruyne MA. Related Articles, NEW Lir
Tongue piercing and associated oral and dental complications.
Endod Dent Traumatol. 2000 Oct;16(5):232-7.
PMID: 11202888 [PubMed - indexed for MEDLINE]

- ☐ 3: Hardee PS, Malliya LR, Hutchison IL. Related Articles, NEW Lir
Tongue piercing resulting in hypotensive collapse.
Br Dent J. 2000 Jun 24;188(12):657-8.
PMID: 11022380 [PubMed - indexed for MEDLINE]

- ☐ 4: Farah CS, Harmon DM. Related Articles, NEW Lir
Tongue piercing: case report and review of current practice.
Aust Dent J. 1998 Dec;43(6):387-9.
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J Can Dent Assoc. 1998 Dec;64(11):803-5. Review.
PMID: 9879145 [PubMed - indexed for MEDLINE]

- ☐ 6: Cobb DS, Denehy GE, Vargas MA. Related Articles, NEW Lir
Adhesive composite inlays for the restoration of cracked posterior teeth associated with a tongue bar.
Pract Periodontics Aesthet Dent. 1998 May;10(4):453-60; quiz 461.
PMID: 9655054 [PubMed - indexed for MEDLINE]

- ☐ 7: Perkins CS, Meisner J, Harrison JM. Related Articles, NEW Lir
A complication of tongue piercing.
Br Dent J. 1997 Feb 22;182(4):147-8.
PMID: 9062002 [PubMed - indexed for MEDLINE]

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